

b) Remarks

Claims 4, 5 and 17-20 have been amended in order to recite the present invention with the specificity required by statute. The subject matter of the amendment is found in the specification as filed, e.g., at page 13, lines 22-29. Accordingly, no new matter has been added.

The Examiner has acknowledged receipt of the certified copy of the priority document and states the drawings are acceptable "for examination purposes." As understood, the drawings therefore are acceptable per se, since the undersigned is unaware of any objections to the drawings. If any corrections are required for issue, the Examiner is respectfully requested to provide clarification in the next Patent Office communication.

Claims 4, 6-16, 19-22 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Since this rejection is not well-understood, the undersigned spoke to the Examiner and learned that this rejection will be overcome by amending the claims to change "derived" to --obtained-- or --isolated--. Accordingly, solely in order to reduce the issues, such has been attended to above.<sup>1</sup>

Claims 4-5 and 17-20 are rejected under 35 U.S.C. §112, second paragraph, as indefinite for the reasons noted. These points have been addressed by the above amendment.

Claims 4, 6-16 and 19-22 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as

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<sup>1</sup> Still, to complete the record, the Examiner's "interpretation" of "derived from" is not at all appropriate and ignores the plain accepted usage of the phrase in this art. "Derive" is to obtain something from a specified source, to arise from or originate in a specified source. It is absurd to assert such could relate, in this context, to "deduction" or "inference". Indeed, there are, per the PTO, over 2100 U.S. patents issued containing both "DNA" and "derived from" in their claims.

to reasonably convey that the inventors, at the time the application was filed, had possession of the claimed invention. In support of the rejection, the Examiner is objecting to the presence of "at least one of deletion, addition, insertion and modification" language in the claims. During various telephone conferences with the Examiner, the undersigned pointed out there is no such language utilized and it was reported the Examiner considers the "derived from" language to encompass additions, deletions, etc. While this is plainly absurd, such is nevertheless overcome by the above amendment.

In this regard, Applicants respectfully submit it is remarkably unhelpful to the advancement of prosecution to interpret claim terms that is anathema to the art-accepted meaning of the language, as well as to the conventional dictionary definitions of the same.

Claims 4, 6-16 and 19-22 stand rejected under 35 U.S.C. §103(a) as being obvious over Vann (*Glycobiology*, 1997, Vol. 7(5):697-701) or Vann (*J. Biol. Chem.*, 1987, Vol. 262(36):17556-62 and Maru (*Carbohydrate Research*, Vol. 306:575-578), and claims 5-18 and 21-22 are rejected as obvious over this art in view of the newly-cited reference to Baker (*BBRC*, July 1998, 248(2):250-254).

The bases for this rejection, while set forth in detail, are also unclear since the Examiner specifically mentioned in the previous June 24, 2002 Office Action that such claims would be allowable. Accordingly, in order to reduce the issues, the undersigned discussed this rejection as well, in detail, with the Examiner during their telephone conversations.

During those conversations, the Examiner stated, once again, the first rejections (over both Vann articles and Maru) would be overcome by the above

amendment<sup>2</sup> deleting "derived from". However, the Examiner stated that the second rejection in view of Baker<sup>3</sup> would not be overcome by that amendment.

Baker annotates *Synechocystis* ORF with accession 1652543 as nucleotide-sugar epimerase by computer homology search. Nucleotide-sugar epimerase (Enzyme Commission Number: E.C. 5.1.3.14) is an enzyme using nucleotide-sugar as a substrate.

Baker relates to producing N-acetylneuraminic acid from UDP-N-acetylglucosamine, which is a nucleotide-sugar, via N-acetylmannosamine using UDP-N-acetylglucosamine 2-epimerase derived from *Synechocystis*, but does not relate to producing N-acetylneuraminic acid from N-acetylglucosamine, which is not a nucleotide-sugar.

N-acetylglucosamine 2-epimerase (N-acylglucosamine 2-epimerase; Enzyme Commission Number: E.C. 5.1.3.8) is an enzyme using N-acetylglucosamine as a substrate. Therefore, N-acetylglucosamine 2-epimerase is an enzyme far different from nucleotide-sugar epimerase in view of both classification and actual activity. Accordingly, there is no *prima facie* obviousness.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.<sup>4</sup>

Claims 4-22 remain presented for continued prosecution.

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<sup>2</sup> Which is, in any event, entirely unnecessary inasmuch as N-acetylglucosamine 2-epimerase obtained from a microorganism had not been known at the time the present application was filed (specification page 1, lines 20 to 21) and homology between Maru's porcine kidney amino acid sequence of N-acetylglucosamine 2-epimerase and SEQ ID NO:1 is only 35.4%.

<sup>3</sup> Which apparently should have included claim 4 as well.

<sup>4</sup> Therefore, if, for any reason at all, this application is not now passed to issue, the next Office Action, if it pertains to claim 4, may not be made "final."

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



Attorney for Applicants  
Lawrence S. Perry  
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO  
30 Rockefeller Plaza  
New York, New York 10112-3801  
Facsimile: (212) 218-2200

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